

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BORMANN et al.

Art Unit: 1723

Application No.: 09/936,732

Examiner: Krishnan S. Menon

Filed: September 17, 2001

For: BIOLOGICAL FLUID FILTER AND SYSTEM

DECLARATION UNDER 37 CFR §1.132 OF BRIAN T. MUELLERS, PH.D.

U.S. Patent and Trademark Office Randolph Building 401 Dulany Street Customer Window Alexandria, VA 22314

Dear Sir:

I, Brian T. Muellers, hereby declare the following:

- 1. I am presently employed by Pall Corporation, East Hills, NY, as a Senior Vice President of Life Science Materials and Applications. I have over 17 years experience in the areas of blood filtration and filtration media with Pall Corporation, beginning as a Laboratory Analyst, Research and Development Chemist, Research and Development Supervisor, Research and Development Product Development Manager, then Director of Filter Media Research, and subsequently a Vice President of Technology Medical Materials.
- 2. I received a Ph.D. in Polymer Chemistry from Polytechnic University of New York in 1998, and I received a M.S. in Chemistry from Polytechnic University in 1996. I received a B.S. in Biology from SUNY in Albany NY, in 1986.
- 3. I am the sole author, or co-author, of at least 3 papers in reviewed Journals, relating to polymer technology, and I am an inventor on nine U.S. Patents.

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- 4. I have reviewed a patent application entitled "Biological Fluid Filter and System," that I understand was filed on September 17, 2001, and given U.S. Patent Application Number 09/936,732 (hereinafter referred to as the "Application"). I have also reviewed an Office Action mailed in the Application on August 18, 2004, and an Advisory Action mailed in the Application on November 10, 2004, as well as the claims referred to (and rejected) in the Office Action and Advisory Action. Additionally, I have reviewed the documents cited in the above-identified Office Action and Advisory Action, particularly European Published Patent Application No. EP 0,267,286 A1 to Nishimura et al. (hereinafter referred to as "Nishimura"), European Published Patent Application No. EP 0,630,675 A1 to Kuroki et al. (hereinafter referred to as "Kuroki"), and U.S. Patent No. 5,547,576 to Onishi et al. (hereinafter referred to as "Onishi").
- 5. The Office Action indicates that "zeta potential as in claim 11 [wherein the filter elements have a negative zeta potential at physiological pH], and CWST as in claims 12, 13, and 15 are all material properties, and would be similar for similar materials."
- 6. I do not understand what the Office Action means by "material properties, and would be similar for similar materials." In particular, I do not understand what the Office Action means by "similar materials."
- 7. However, to the extent that the Office Action may be interpreted as concluding that Nishimura, Kuroki and/or Onishi disclose media inherently having a negative zeta potential at physiological pH, or having different predetermined Critical Wetting Surface Tensions (CWSTs), or having a CWST of at least about 90 dynes/cm, I believe, based upon my knowledge and experience, that these conclusions in the Office Action are incorrect.
- 8. Upon reviewing Nishimura, Kuroki, and Onishi, I do not believe they provide sufficient information to determine the zeta potential. Based upon my knowledge and experience, to the extent that they provide information, they suggest elements with a positive zeta potential.
- 9. Nishimura teaches using nitrogen-containing basic functional groups, and provides the following examples of nitrogen-containing basic functional groups: "a primary amino group, a secondary amino group, a tertiary amino group, and a quaternary ammonium group, and also include nitrogen-containing aromatic ring groups such as a pyridyl group and an imidazolyl group" (page 9, lines 18-24). The nitrogen-containing basic functional groups

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described in Nishimura will all be expected to shift the zeta potential to the positive side due to the proton donating, i.e., basic nature, of these groups.

- 10. Kuroki teaches a "cationic treatment" (e.g., page 5, line 9), and indicates usable cationic compounds are "quaternary ammonium salts, compounds having amino groups or imino groups, etc." (page 5, lines 13-14). The cationic compounds described in Kuroki will also shift the zeta potential to the positive side due to the basic nature of these groups.
- 11. Onishi teaches immobilizing a polyamine compound, and provides a list of polyamine compounds at column 5, line 59 through column 7, line 11. The polyamine compounds described in Onishi will also shift the zeta potential to the positive side due to the basic nature of these groups.
- 12. I do not believe Nishimura, Kuroki and/or Onishi provide sufficient information to provide an element with a predetermined CWST, or two elements with different predetermined CWSTs, or elements with CWSTs of at least about 90 dynes/cm. There is no mention of CWST in any of Nishimura, Kuroki, and Onishi, and I am unable to determine the CWSTs of the elements disclosed in these 3 documents.
- 13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further than these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2/14/2005

Brian T. Muellers, Ph.D.